

FluvaxTM Inactivated Influenza Vaccine (Split Virion)

CSL Biotherapies

MATERIAL SAFETY DATA SHEET
Page 1 of 4 - Date of Issue: 20 August 2010

IMPORTANT NOTICE This Material Safety Data Sheet (MSDS) is prepared by CSL Limited in accordance with the Australian National Occupational Health & Safety Commission National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(2003)]. The information contained herein must not be altered or deleted. Additional information may be appended to the MSDS, but it must be marked clearly to indicate that it is not part of the original.

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name FluvaxTM Inactivated Influenza Vaccine (Split Virion)

Other Names EnziraTM, AfluriaTM, NilgripTM, X-FluTM, Influenza Vaccine Ph. Eur.

Manufacturer's Product Code 09060101, 09060104, 09060119, 09060117, 09060818, 09863001, 09863007, 09862701, 09862707, 09060125, 09062707, 09062555, 09862401, 09862407, 09161001, 09160107

Use For the prevention of influenza caused by Influenza Virus, types A and B.

Supplier Name CSL Limited (ABN 99 051 588 348)

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U.S. CSL Behring (610) 878-4000

U.S. Emergency Response: (800) 424-9300

U.S. Emergency Product Information: (800) 504-5434

2. HAZARDS IDENTIFICATION

Not classified as hazardous according to the criteria of NOHSC
Not classified as a dangerous good by the criteria of the ADG Code

3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Name:</i>	<i>CAS Number:</i>	<i>Proportion:</i>
Inactivated Influenza Virus Strains	-	90mcg/mL
Calcium Chloride	10043-52-4	trace
Neomycin	-	trace
Polymyxin	-	trace
Other non-hazardous ingredients	-	<10%
Thimerosal	-54-64-8	0.01% w/v (multi-dose vial only)
Water for injections		up to 100%

4. FIRST AID MEASURES

Eye Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek immediate medical attention.

Swallowed DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. If sensitive to eggs, feathers or other ingredients, seek medical attention immediately.

Skin Remove contaminated clothing. Wash skin thoroughly with water. If irritation occurs, seek medical attention.

Aggravated Medical Conditions Fluvax™ is prepared from virus grown in the allantoic cavity of embryonated eggs, therefore individuals with anaphylactic hypersensitivity to eggs and/or chicken feathers, neomycin, polymyxin or any other component of the vaccine should avoid direct contact with Fluvax™. This would include persons whom upon ingestion of eggs, develop swelling of the lips or tongue or experience acute respiratory distress or collapse.

Advice To Doctor Treat symptomatically. Cases of anaphylaxis may require treatment with adrenaline, oxygen, intravenous steroids and airway management including intubation.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard Not considered a significant fire risk.

Fire Extinguishing Media No restrictions.

Hazchem Code None allocated

6. ACCIDENTAL RELEASE MEASURES

Minor Spills

- Clean up spill immediately using absorbent paper towels.
- Wear protective gloves and safety glasses.
- Place spilled material in clean, dry, sealed container for disposal.
- Wash area with copious amounts of water.

Major Spills

- Wear protective gloves and safety glasses.
- Contain and absorb spills using earth, sand or inert absorbent.
- Collect residues and seal in labelled drums for disposal.
- Wash area with copious amounts of water.

7. HANDLING AND STORAGE

- Transport and store at 2 to 8 degrees C (do not freeze).
- Protect from light.
- Store as per Schedule 4 pharmaceutical.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by NOHSC or ACGIH

Engineering Controls None under normal operating conditions.

Personal Protection For good infection control, gloves should be worn when administering an injection.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	A clear to slightly opaque liquid containing some sediment, which readily resuspends upon shaking, in a pre-filled syringe with attached needle, and multi-dose vials.
Odour	None
pH	6.9-7.4
Boiling Point/Melting Point	Not Determined
Vapour Pressure	Not Determined
Vapour Density	Not Determined
Specific Gravity	Not Determined
Flashpoint	Not Determined
Flammability Limits	Not Determined
Solubility in Water	Aqueous solution

10. STABILITY AND REACTIVITY

Reactivity	Not known to be incompatible with other materials.
Stability	Stable under anticipated storage and handling conditions (refer section 7).
Decomposition Products	Not Determined

11. TOXICOLOGICAL INFORMATION

Eye	May cause mild irritation. In hypersensitive individuals, may precipitate an acute allergic reaction. Local swelling may be accompanied by systemic symptoms. See under Acute Effects, Swallowed.
Swallowed	May cause mild irritation of the gastro-intestinal tract. In hypersensitive individuals, may precipitate an acute allergic reaction. Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; skin rash, itching or hives.
Skin	May cause mild irritation.
Inhaled	Not an expected route of exposure.
Chronic Health Effects	No chronic health effects expected under conditions of use.

12. ECOLOGICAL INFORMATION

MATERIAL SAFETY DATA SHEET

FluvaxTM Inactivated Influenza Vaccine (Split Virion)

Page 4 of 4
Date of Issue: 20 August 2010

- No data available.
- For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.

14. TRANSPORT INFORMATION

UN Number None allocated
DG Class None allocated
Subsidiary Risk None allocated
Packing Group None allocated
Hazchem Code None allocated

15. REGULATORY INFORMATION

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

16. OTHER INFORMATION

Last Revised 20 August 2010

Reason for Revision Section 1: U.S. Telephone Number Update, add codes for MDV and PFS
Section 3: add thimerosal as ingredient for MDV only, proportion correction

Abbreviations

NOHSC – National Occupational Health and Safety Commission (please note NOHSC information can be sourced from www.ascc.gov.au)
ACGIH – American Conference of Governmental Industrial Hygienists
ADG Code – Australian Dangerous Goods Code
UN Number – United Nations Number
DG Class – Dangerous Goods Class
CAS Number – Chemical Abstract Service Number

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